

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris</p>
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p><b>PLAINTIFFS' JOINT SURREPLY IN FURTHER OPPOSITION TO DEFENDANT MEDIMMUNE, INC.'S INDIVIDUAL MOTION TO DISMISS</b></p>

*County of Genesee v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-00267

*County of Greene v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0474

*County of Herkimer v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-00415

*County of Jefferson v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0715

*County of Lewis v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0839

*County of Madison v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-00714

*County of Monroe v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6148

*County of Nassau v. Abbott Laboratories, Inc., et al.*  
E.D.N.Y. Case No. 04-CV-05126

*County of Niagara v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-06296

*County of Oneida v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0489

*County of Onondaga v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0088

*County of Ontario v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6373

*County of Orleans v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6371

*County of Putnam v. Abbott Laboratories, Inc., et al.*  
S.D.N.Y. Case No. 05-CV-04740

*County of Rensselaer v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-00422

*County of Rockland v. Abbott Laboratories, Inc., et al.*  
S.D.N.Y. Case No. 03-CV-7055

*County of Schuyler v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6387

*County of Seneca v. Abbott Laboratories, Inc., et al.*

W.D.N.Y. Case No. 05-CV-6370

*County of St. Lawrence v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0479

*County of Saratoga v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0478

*County of Steuben v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6223

*County of Suffolk v. Abbott Laboratories, Inc., et al.*  
E.D.N.Y. Case No. 03-CV-12257

*County of Tompkins v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0397

*County of Ulster v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 06-CV-0123

*County of Warren v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0468

*County of Washington v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0408

*County of Wayne v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-06138

*County of Westchester v. Abbott Laboratories, Inc., et al.*  
S.D.N.Y. Case No. 03-CV-6178

*County of Wyoming v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6379

*County of Yates v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-06172

MedImmune's reply memorandum ("MedImmune Reply"),<sup>1</sup> makes two critical admissions that soundly establish plaintiffs' fraud claims based on false WACs and AWPs, thus defeating its motion to dismiss: 1) drugs described as "physician administered" like Synagis can and are reimbursed based on AWP, and 2) that, as alleged in the CC, administration costs are factored into the AWP spread of Synagis. *See* MedImmune Reply at 2-3, fn 6. By doing so, MedImmune bolsters both the irrelevance of the "physician administered" label to plaintiffs' claims and the fraudulent nature of its AWPs.

MedImmune maintains that plaintiffs' allegations related to its "physician administered" drugs do not establish a reasonable inference of fraud because (i) plaintiffs did not allege that MedImmune represented AWP and WAC to reflect actual cost nor did plaintiffs define AWP or WAC; (ii) MedImmune's drugs were reimbursed at "actual cost" pursuant to New York Statute; and (iii) plaintiffs only allege spread for one of the three drugs named in their complaints.

MedImmune's argument is misguided and incorrect. The fact that a physician is reimbursed at "actual cost" is irrelevant to plaintiffs' claims concerning reimbursement for MedImmune drugs based on AWP. MedImmune admits its drugs were reimbursed on the basis of AWP, as plaintiffs allege, and MedImmune admits that its AWPs do not merely reflect an average of wholesale prices but include an extra amount to cover "administration services", as plaintiffs also allege. In addition, MedImmune is incorrect to suggest that plaintiffs are required to plead a specific spread for every MedImmune drug at issue. *See* MedImmune Opp. at 2. Moreover, MedImmune's admission that its AWPs are inflated to cover "administration services" (in addition to making no sense given that those who actually administer its drugs are typically not reimbursed based on AWP) by itself confirms that MedImmune's AWPs do not reflect true

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<sup>1</sup>For clarity and consistency, plaintiffs use the same definitions of all terms and cases cited in their corresponding individual opposition memorandum ("MedImmune Opp."). Additionally, all other causes not addressed herein are addressed in Plaintiffs Consolidated Sur-Reply to Defendants Motion to Dismiss, filed contemporaneously herewith (referred to herein as "Consolidated Sur-Reply").

wholesale prices and that plaintiffs' allegations of fraudulent inflation are made in entirely good faith. The following summarizes why MedImmune's motion should be denied in its entirety:

*First*, MedImmune admits -- as it must -- that "physician administered" drugs like Synagis are reimbursed at AWP as well as at "actual cost" under New York Medicaid.<sup>2</sup> *See* MedImmune Reply at 2. Synagis is distributed by "Assignment of Benefit Distributors, who are reimbursed at AWP minus a percentage." MedImmune Reply at 3.

*Second*, plaintiffs' claims concern reimbursements made to health care providers, including specialty pharmacies, based on the drug NDC and corresponding AWP.<sup>3</sup> *See* CC at ¶¶ 5, 83-85; NSAC at ¶¶ 69-73. *See also* N.Y. Soc. Sev. L. §367-a(9)(ii).

*Third*, Synagis, like all MedImmune drugs, has been reimbursed by New York Medicaid to providers at AWP.<sup>4</sup>

*Fourth*, MedImmune contends it never represented that AWP or WAC means actual cost.

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<sup>2</sup>The phrase "physician administered" has no operative or controlling significance in terms of reimbursement under New York Medicaid or whether such reimbursement is based on AWP. The Statute provides that New York Medicaid reimburses "for drugs provided by medical practitioners and claimed separately by the practitioners, [at] the actual cost of the drugs to the practitioners." N.Y. Soc. Serv. Law §367-a(9) (emphasis added). Thus, in order for a physician administered (or any other) drug to be reimbursed at "actual cost", the "medical practitioner" must: (i) provide the drug; and, (ii) claim reimbursement separately. *See id.* Plaintiffs concede that the plain meaning of the statute says that drugs so provided and claimed are reimbursed based on actual cost.

<sup>3</sup>MedImmune implies that plaintiffs seek to equate the reimbursement of physicians at "actual cost" under New York Medicaid with either WAC or AWP. They are not.

<sup>4</sup>In January 1999, the NY Department of Health ("NY DOH") issued a Medicaid Update entitled "Medicaid Coverage Of SYNAGIS (PALIVIZUMAB)" addressing the reimbursement of Synagis:

"Medicaid reimburses for **SYNAGIS** when billed by Medicaid-enrolled physician and pharmacy providers. It can be administered in the home by Medicaid-enrolled Home Health Care provider professional staff. Similarly, it can be administered by pediatric long term care facility licensed caregivers. Physician providers may bill on a paper claim under code **90749** (unlisted immunization procedure), attaching a copy of the invoice to the claim. [...] Pharmacy providers should enter the SYNAGIS NDC number into the on-line billing system as they would for any prescription pharmaceutical" (bold in original, emphasis added)."

*See* [http://www.health.state.ny.us/health\\_care/medicaid/program/update/1999/0199med.htm#coverage](http://www.health.state.ny.us/health_care/medicaid/program/update/1999/0199med.htm#coverage). Of note is that physician providers submit a J-Code (in bold above) for reimbursement, while the providers submit an NDC for reimbursement. Certainly MedImmune knew this.

Also, in May 2001, the NY DOH issued a Medicaid Update entitled "Attention Pharmacy Providers Serving Nursing Home & Child Care Agencies" informing Pharmacy Providers to Nursing Homes and Child Care Facilities of drugs for which they may seek reimbursement, including Synagis, Respigam and Cytogam and many other "physician administered" drugs. *See* [http://www.health.state.ny.us/health\\_care/medicaid/program/update/2001/may2001.htm#att](http://www.health.state.ny.us/health_care/medicaid/program/update/2001/may2001.htm#att)

Reply at 1. But actual costs are not the issue here; accurate AWPs are. MedImmune is legally obligated to report true wholesale pricing information to the government in order to have its products paid for from the public fisc.<sup>5</sup> *See North Memorial Medical Center v. Gomez*, 59 F.3d 735, 739 (8<sup>th</sup> Cir. 1995) (*citing Heckler v. Community Health Servs.*, 467 U.S. 51, 64-65 (1984)). Plaintiffs allege that it does not do so.

*Fifth*, MedImmune admits that the AWP for Synagis is used “to cover the extraordinary costs encountered in administering Synagis”. MedImmune Reply at fn 6. In addition to conceding a false inflation of AWP, the argument makes no practical sense. Physicians or practitioners seeking reimbursement for administering Synagis do so based on J-Codes, which includes compensation for the administering service. Those reimbursed for Synagis based on AWPs are not “practitioners” or others incurring administering service costs. Why should MedImmune be charging Medicaid for a service that is not provided? Moreover, even if an administering service were provided by those reimbursed based on AWP, the plain meaning of AWP is “average wholesale price” not “average wholesale price + administering service cost”. This admission by MedImmune, even without a spread, establishes a strong inference of fraud that MedImmune’s AWPs are false.

*Sixth*, plaintiffs’ response to MedImmune contention that plaintiffs’ allegations lack specificity for Best Price claims is set forth at Point IV of their Consolidated Sur-Reply, which is incorporated herein.

*Seventh*, MedImmune does not dispute -- nor can it -- that prior to June 9, 1994 New York Medicaid reimbursed all MedImmune drugs to all claimants based on AWP, irrespective of any “physician administered” description. *See* MedImmune Reply at 3.

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<sup>5</sup> MedImmune also claims that plaintiffs “have not alleged, if ever, they paid for MedImmune drugs based on allegedly inflated AWPs or WACs.” *Id.* at 3. To the contrary, that is exactly what they have done., *See* CC at ¶¶589-590; NSAC at ¶¶ 489-496.

**CONCLUSION**

For the reasons set forth herein and in Plaintiffs' Opposition Memorandum, MedImmune's individual Motion to Dismiss should be denied in its entirety.

Dated: June 2, 2006

Respectfully submitted,

**City of New York and all captioned Counties  
except Nassau, by**

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